REV-01
BPH/63/16/19

2022/12

SET A

B. PHARM.
SEVENTH SEMESTER
INDUSTRIAL PHARMACY II
BP702T
[USE OMR SHEET FOR OBJECTIVE PART]

Duration : 3 hrs. **Full Marks : 75**

[PART-A: Objective]

Time : 30 min. **Marks : 20**

Choose the correct answer from the following: ***1×20=20***

1. Which of the following method is used for liquid filling?
   a. Gravimetric
   b. Volumetric
   c. Constant level method
   d. All of the above

2. Self life of a drug is determined by
   a. Stability study
   b. Chemical analysis
   c. Assay
   d. Pharmacovigilance

3. MFC is prepared by?
   a. Production
   b. R&D
   c. QA
   d. QC

4. GMP stands for?
   a. Good manufacturing practices
   b. Good material purchase
   c. Goods material procurement
   d. None of the above

5. Key components of TQM?
   a. Consumer/Customer focus
   b. Continuous improvement
   c. Involvement of employee
   d. All of the above

6. What is a synonym/description for the phase 4 trials?
   a. Post marketing surveillance
   b. Pre market surveillance
   c. Pre FDA approval
   d. Post FDA approval

7. What is purpose of NDA?
   a. Sale and marketing
   b. Clinical trial
   c. Market survey
   d. None of the above

8. COPP is recommended by
   a. WHO
   b. CDSCO
   c. State
   d. None of the above

9. Head of central drug testing laboratory-
   a. Drug controller of India
   b. Director general of health services
   c. DCGI
   d. None of the above

10. Basic principle of ISO 9000-
    a. Customer focus and engagement of people
    b. Relationship management and leadership
    c. Evidence based decision making and continuous improvement
    d. All of the avove

11. Six sigma concept includes
    a. Define, Measure, Analyse, Improve and control
    b. Design, Measure, Analyse, Improve and control
    c. Define, manage, Analyse, Improve and control
    d. All of the above

12. Phase I clinical trial gives idea about
    a. Safety and tolerability
    b. Side effects
    c. Toxicity
    d. Post market survey

13. Phase II clinical trial gives idea about
    a. Safety and tolerability
    b. Side effects
    c. Toxicity
    d. Post market survey

14. Definition of Quality risk management has been mentioned in ICH guideline
    a. Q7
    b. Q8
    c. Q9
    d. Q3

15. The transfer of technology between sites of different companies is called as
    a. Inter-company transfer
    b. Intra- company transfer
    c. Technology transfer
    d. Technology transfer protocol

16. ICH Q3 guideline for
    a. Stability
    b. Impurity
    c. Validation
    d. QRM

17. Quality control is defined as _____?
    a. Sampling and documentation
    b. Sampling, Specification and documentation
    c. Sampling, specification, testing, documentation and release procedures
    d. None of the above

18. ICH involves ?
    a. Quality, safety
    b. Quality, safety and efficacy
    c. Quality control and multidisciplinary guidelines
    d. Quality, safety, efficacy and multidisciplinary guidelines

19. Pilot Plant can be used for ?
    a. Evaluating results for laboratory
    b. Product and process correction
    c. Shelf life and stabilities studies
    d. All of the above

20. Which of the following is not a scale-up process?
    a. Laboratory to pilot Scale
    b. Pilot scale to industrial scale
    c. Industrial to Pilot Scale
    d. Laboratory to Industrial Scale

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PART-B :Descriptive

Time : 2 hrs. 30 min. Marks : 35

[Answer any seven (7) questions]

1. What do you mean SUPAC? Write its significance in pilot plant. 5
2. Write critical aspects of semisolid manufacturing 5
3. Write five objectives of TQM and QBD 5
4. Define terms- API, Excipients, DQ, IQ, PQ 5
5. Mention technology transfer protocol. 5
6. Mention parts of clinical research protocol. 5
7. Mention functions of GMP and its advantages and disadvantages. 5
8. Write functions of CDSCO. 5
9. Write a note on documents required for applying for granting or revalidation of COPPs. 5

PART-C: Long type questions

[Answer any two (2) questions]

1. Define technology transfer. What is sending unit and receiving unit? Write the principles of technology transfer. 10
2. What do you mean by Out of specification? Write a note on Six sigma process. Write two advantages of NABL. 10
3. What are the regulatory requirements and approval procedures for new drugs? 10

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